

**REMARKS**

The Office Action dated March 10, 2005, has been received and reviewed.

Claims 1-22 are currently pending and under consideration in the above-referenced application. Of these claim 17 has been objected to for depending from a rejected base claim, while claims 1-16 and 18-22 stand rejected.

Reconsideration of the above-referenced application is respectfully requested.

**Rejections Under 35 U.S.C. §102**

Claims 1-3, 7-16, and 18-22 stand rejected under 35 U.S.C. § 102(b) for reciting subject matter which is purportedly anticipated by the subject matter described in U.S. Patent 5,080,895 to Tokoro (hereinafter “Tokoro”)

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

With respect to inherency, M.P.E.P. § 2112 provides:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) . . . ‘To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill . . .’’ *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1991).

M.P.E.P. § 2112 clearly places the burden of showing inherency on the Examiner.

It is not Applicant’s burden to show that the chickens of Tokoro were not exposed to an antigen that would have caused them to elicit a T-cell mediated immune response, that eggs laid by the chickens disclosed in Tokoro would not have included transfer factor, or that administration of an extract of such eggs would not have caused a treated animal to elicit a T-cell

mediated immune response. Rather, under M.P.E.P. § 2112, the burden to shown inherency is clearly on the Examiner—in this case, it is the Examiner’s responsibility to show that the chickens in Tokoro would *necessarily* have been exposed to an antigen that would elicit a T-cell mediated immune response and that transfer factor would *necessarily* have been present in the an extract of the chickens’ eggs in sufficient amounts to cause an animal to whom an extract is administered to elicit a T-cell mediated immune response.

The description of Tokoro is limited to generating antibodies (*i.e.*, a B-cell response) against three antigens: the porcine enterotoxic *E. coli* (ETEC) 987P, K88, and K99 antigens. As has already been established, Tokoro does not expressly describe that transfer factor would be present in the eggs of a chicken that has been immunized with any of these antigens. Further, the art indicates that none of these three antigens is necessarily capable of causing an exposed or infected animal to elicit a T-cell mediated immune response. Thus, transfer factor would not necessarily be present in eggs laid by a hen that has been immunized with any of the 987P, K88, and K99 antigens. If transfer factor is not necessarily present in an egg laid by a chicken that has been exposed to or infected by any of these three antigens, administration of the egg or an extract thereof will not necessarily cause a treated animal to elicit a T-cell mediated immune response in the treated animal. Consequently, Tokoro does not expressly or inherently describe that administering an extract of an egg would comprise any transfer factor, let alone enough to initiate a T-cell mediated immune response in the source animal.

Moreover, a chicken would not necessarily be exposed to some antigen that would cause the chicken to elicit a T-cell mediated immune response and produce eggs that include transfer factor. As those of ordinary skill in the art are well aware, animals, including chickens, may be raised in controlled environments. Thus, it is possible to prevent exposure of a chicken to any antigens, including Newcastle Disease Virus, against which the chicken would mount a T-cell mediated immune response. As such, chickens are not necessarily exposed to Newcastle Disease Virus vaccine or any other antigens that might cause them to elicit a T-cell mediated immune response.

Further, Tokoro does not expressly or inherently describe that the “transfer factor-like component” of the eggs described therein would be useful for eliciting a T-cell mediated immune

response or present in amounts sufficient to elicit a T-cell mediated immune response in a treated animal.

As such, Tokoro does not anticipate each and every element of independent claim 1 or independent claim 20.

Claims 2, 3, 7-16, 18, 19, and 22 are each allowable, among other reasons, for depending directly or indirectly from claim 1, which is allowable.

Claim 19 is additionally allowable since Tokoro includes no express or inherent description that there is a sufficient amount of transfer factor in any of the compositions disclosed therein to cause an animal to which the composition is administered to elicit a T-cell mediated immune response *in vivo*.

Claim 22 is further allowable since Tokoro lacks any express or inherent description that administration of an extract of the eggs disclosed therein to a treated animal would enhance the ability of the immune system of the treated animal to elicit an increased T-cell mediated immune response relative to the treated animal's normal T-cell mediated immune response to at least one antigenic agent.

Claim 21 is allowable, among other reasons, for depending directly from claim 20, which is allowable. Claim 21 is also allowable since Tokoro includes no express or inherent description that there is a sufficient amount of transfer factor in any of the compositions disclosed therein to cause an animal to which the composition is administered to elicit a T-cell mediated immune response *in vivo*.

In view of the foregoing, it is respectfully requested that the 35 U.S.C. § 102(b) rejections of claims 1-3, 7-16, and 18-22 be withdrawn.

#### **Rejections Under 35 U.S.C. § 103(a)**

Claims 4-6 have been rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is allegedly unpatentable over the subject matter taught in Tokoro, in view of teachings from U.S. Patent 5,840,700 to Kirkpatrick et al. (hereinafter "Kirkpatrick").

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.  
*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Claims 4-6 are each allowable, among other reasons, for depending directly from claim 1, which is allowable. Claims 4-6 are additionally allowable because, without improperly relying upon the hindsight provided by the disclosure of the above-referenced application, one of ordinary skill in the art would not have been motivated to combine teachings relating to obtaining transfer factor from mammalian tissues (Kirkpatrick) with teachings that relate to the presence of a non-transfer factor, transfer factor-like substance in eggs (Tokoro).

Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejections of claims 4-6 is respectfully solicited.

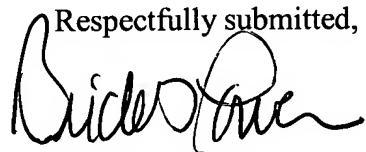
#### **Allowable Subject Matter**

The indication that claim 17 is drawn to subject matter that is allowable over the art of record is noted with appreciation. Claim 17 has not been amended to independent form, however, as claim 1, from which it depends, is believed to be allowable.

#### **CONCLUSION**

It is respectfully submitted that each of claims 1-22 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of

the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,  


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